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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,879	10/27/2005	Bengt Guss	0825-0173PUS2	2276

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EXAMINER

GANGLE, BRIAN J

ART UNIT	PAPER NUMBER
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1645

NOTIFICATION DATE	DELIVERY MODE
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06/25/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/530,879	Applicant(s) GUSS ET AL.	
	Examiner Brian J. Gangle	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7,8,10,12,13 and 15-22 is/are pending in the application.
- 4a) Of the above claim(s) 2,4,5,7,8,10,12,13,15-19,21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/22/05,11/28/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I and the combination of EAG, SEC, and SclC in the reply filed on 3/26/2008 is acknowledged. The traversal is on the following ground(s):

Applicant argues:

1. That the disclosure of Lindmark does not breed unity because it is not a "novelty-destroying disclosure." Applicant asserts that the protein EAG has not been disclosed in the prior art and the protein ZAG has not been indicated to have immunogenic properties. Applicant asserts that while the gene for EAG has been disclosed, the protein has not, and it has not been disclosed that the gene is expressed in naturally occurring *S. equi* subsp. *equi*. Applicant further asserts that recombinant EAG is therefore novel as are compositions comprising it.

2. That a search and examination burden is required for a restriction to be proper. Applicant asserts that, since EAG links all of the inventions, a search of the literature for this protein, and any composition comprising it, would not be a burden.

3. That the restriction is improper because the compositions should be considered as subcombinations of generic claims directed to compositions comprising EAG. Applicant asserts that a species election should have been used concerning the various combinations of "antigens comprising the recombinant EAG protein."

Applicant's arguments have been fully considered and deemed non-persuasive.

Regarding argument 1, it is noted that there is no mention of recombinant EAG in the claims. According to the instant specification (page 9, lines 20-26), the EAG protein is found in natural *S. equi* subsp. *equi*. Whether or not this was previously recognized is immaterial. The fact is that *S. equi* subsp. *equi* species contained the protein. Therefore, a culture containing these bacteria (such as disclosed by Lindmark) is an antigenic composition comprising EAG. Therefore, the feature that links the claims is not novel and restriction is proper.

Regarding argument 2, applicant has filed the instant application as the national stage of a PCT application. Therefore, search and examination burden is not a consideration when determining the propriety of restriction in this case.

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Regarding argument 3, the restriction practice to which applicant refers (combination/subcombination) is used in determining whether inventions are distinct in US restriction practice. However, as stated above, applicant chose to file the instant case under 35 USC 371; therefore, the lack of unity rules apply. As set forth previously, there is no special technical feature linking the inventions and restriction is proper.

The requirement is still deemed proper and is therefore made FINAL.

New claims 21 and 22 are added. Claims 1-5, 7-8, 10, 12-13, 15-22 are pending. New claim 21 is part of Group I as set forth in the restriction requirement. New claim 22 is part of Groups VII and VIII as set forth in the restriction requirement. Claims 2, 4-5, 7-8, 10, 12-13, 15-19, and 21-22 are withdrawn as being drawn to nonelected inventions. Claims 1, 3, and 20 are currently under examination.

Information Disclosure Statement

The information disclosure statements filed on 6/22/2005 and 11/28/2005 are acknowledged. Initialed copies are enclosed.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 3, and 20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention is drawn to a protein product of nature. Products of nature are not patentable because they do not reflect the "hand of man" in the production of the product or manufacturing process. Diamond v. Chakrabarty, 206 USPQ 193 (1980). As disclosed in the instant specification, the three antigens, EAG, SEC, and Scl are found naturally in *S. equi* subsp. *equi*. Therefore, the bacteria themselves are an antigenic composition comprising these antigens.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 is rendered vague and indefinite by the phrase “comprises at least part of a protein designated Scl and comprising an amino acid sequence according to SEQ ID NO:23 or a fragment thereof, suitably a fragment designated SCL C1 and comprising an amino acid sequence according to SEQ ID NO:27 or an analog thereof.” The use of the term “suitably” makes it unclear whether the limitation following the phrase (i.e., a fragment designated SCL C1 and comprising an amino acid sequence according to SEQ ID NO:27) is part of the claimed invention. Further, from the claim language, it appears that SCL C1 (SEQ ID NO:27) is a fragment of Scl (SEQ ID NO:23). However, an examination of these sequences reveals that SEQ ID NO:27 is not a fragment of SEQ ID NO:23. Finally, it is not clear whether the phrase "or an analog thereof" is meant to apply to SEQ ID NO:23, a fragment of SEQ ID NO:23, or SEQ ID NO:27.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Lindmark *et al.* (Res. Vet. Sci., 66:93-99, 1999, IDS filed 6/22/2005).

The instant claims are drawn to antigenic compositions comprising at least one antigen, wherein said at least one antigen comprises at least part of a protein of *Streptococcus equi* subsp *equi*, and said at least part of said protein comprises at least one antigenic epitope or antigenic determinant of *Streptococcus equi*, and wherein said protein is comprised of EAG comprising an amino acid sequence according to SEQ ID NO: 1, or an analog thereof (claim 1), comprising at least one further antigen that comprises at least part of a protein of *Streptococcus equi* and said at least part of said protein comprises an antigenic epitope or an antigenic determinant of *Streptococcus equi*, and wherein said protein is comprised of SEC comprising an amino acid

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sequence according to SEQ ID NO: 4, or an analog thereof (claim 3), comprising at least part of a protein designated Scl and comprising an amino acid sequence according to SEQ ID. NO:23 or a fragment thereof, suitably a fragment designated SCL C1 and comprising an amino acid sequence according to SEQ. ID. NO:27, or an analog thereof (claim 20).

Lindmark *et al.* disclose a composition containing *S. equi* subsp. *equi* cells (see page 94, column 2, paragraph 3). As disclosed in the instant specification, each of the claimed antigens (SEQ ID NOs 1, 4, and 23) are found naturally in *S. equi* subsp. *equi*. Therefore, the composition of *S. equi* subsp. *equi* cells disclosed by Lindmark necessarily comprises at least part of EAG, SEC, and Scl.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571)272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian J Gangle/
Examiner, Art Unit 1645

/Shanon A. Foley/
Supervisory Patent Examiner, Art Unit 1645